REMARKS

In an Office Action dated January 28, 2004, claims 15-16 and 18-26, all of the claims under consideration in the subject patent application were rejected. By amendment above, claims 15 and 18 have been rewritten. Support for the amendment to claims 15 and 18 can be found on page 7, line 12 to page 8, line 14 of the specification.

Reconsideration of this application and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 15-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Soma et al (US 5,494,819). The Examiner asserts that these claims are drawn to a product prepared from gram negative bacteria, having a molecular weight of 5000 ± 2000 as measured by the SDS-PAGE method, which product is also taught by Soma et al (US 5,494,819). The intended use as a feed composition for crustaceans and fish does not impart any critical impact or weight on the physical preparation and the patentability of the product, in the Examiner's view. According to the Examiner, Soma et al teach a product prepared from gram negative bacteria, having a molecular weight of 5000 ± 1000 as measured by the SDS-PAGE method. The Examiner further asserts that Soma et al teach that this product is a low molecular weight lipopolysaccharide (LMW-LPS) capable of activating immunity, which can be used as feed or feed additive for veterinary use. According to the Examiner Soma et al teach that the LPS is a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 by SDS-PAGE analysis, whereby one of the LPS's is produced by a strain of species Pantoea agglomerans. Finally, the Examiner also has indicated that he does not have the ability to verify any differences between the product of the present invention with the product of Soma et al.

Applicants submit that the present invention is directed to a feed composition for crustaceans or fish comprising as a feed-stuff additive highly purified LMW-LPS and to a method of activating immunity using the feed stuff additive. As is described on page 8, lines 1-14 of the specification, the present LMW-LPS is obtained by subjecting the LPS obtained by Soma et al. (U.S. 5,494,819, which is JP-A-4-99481), to gel filtration in the presence of a surface-active agent to recover only low molecular weight LPS-containing fractions wherein the high molecular weight LPS is removed.

Applicants submit that Soma et al disclose a lipopolysaccharide (LPS) composition which is partially purified, also containing high molecular weight LPS, as a feed or feed additive. For example, Fig. 1 of the specification of Soma et al. illustrates that the LPS disclosed also contains HMW-LPS as HMW-LPS is clearly indicated in Fig. 1. In contrast to Soma et al, in the present invention the feed-stuff additive LMW-LPS is further purified by removing HMW-LPS. Therefore, the feed-stuff additive LMW-LPS of claim 15, as amended, is different from the LPS material in Soma et al, because the LPS material of Soma et al is further purified in the present invention to no longer contain HMW-LPS.

Therefore, the invention as presently claimed is substantially different from the LPS material of Soma et al as not all limitations of the presently claimed invention are disclosed in Soma et al. Applicants respectfully submit that the presently claimed invention of independent claim 15 and dependent claim 16, is not anticipated by Soma et al (US 5,494,819). Withdrawal of the rejection is respectfully requested.

Claims 18-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al (US Patent No. 5,641, 761) in view of Soma et al (US Patent No. 5,494,819). According to

the Examiner the claims are drawn to a method of activating immunity or preventing infection in crustaceans and fish comprising administering an effective amount of LMW-LPS to crustaceans and fish. The Examiner asserts that Takahashi et al teach a method of activating immunity, preventing infection in crustaceans, or treating crustaceans' infections comprising administering or feeding a polysaccharide to crustaceans. The Examiner acknowledges that Takahashi et al do not teach the use of LMW-LPS. However, the Examiner asserts that because Soma et al teach a LMW-LPS capable of activating immunity, as feed or feed additive for veterinary use, it would have been have been obvious to modify the method of Takahashi et al by using the product of Soma et al to obtain the disclosed invention. According to the Examiner one would have been motivated to replace the HMW-LPS of Takahashi et al with the LMW-LPS of Soma et al which has excellent immuno-stimulating activity and may be provided at low cost and in a large amount.

Applicants submit that Takahashi et al teach the use of a particular polysaccharide in feed for crustaceans and fish to activate immunity, prevent infection and treat infections in crustaceans. Takahashi et al use a polysaccharide derived from mushrooms. They also noted that it was suggested in the literature that polysaccharide from yeast (bacteria) exhibits similar biological activities. However, Takahashi et al. stated that it was difficult to confirm their effects against infectious diseases of crustacea. Thus, Takahashi et al suggests that the effect of a polysaccharide in activating immunity in one animal does not confirm the same effect in crustaceans. Soma et al merely teaches that LMW-LPS in feed for veterinary use activates immunity in animals. However, Soma et al do not teach or suggest that the use of LMW-LPS in feed for crustaceans and fish activates immunity. Moreover, it is known that there are substantial

differences in the defense mechanisms of crustaceans and fish compared to mammals, as discussed for example on page 3, line 24 to page 4, line 4 of the specification. Crustaceans have no ability to produce an antibody or a lymphocyte, neutrophile or basophile as found in a vertebrate. Fishes have a limited ability to produce an antibody and their production of antibodies is greatly affected by the water temperature as they are cold-blooded animals. Therefore such immune system functions insufficiently to prevent or fight against infections. The substantial difference in defensive mechanisms between these oceanic organisms and mammals as described for example in Fish Pathology, 30(2), 141-150, June in 1995; and Fish Pathology 94-97 (1978) "Vaccine for vivrio diseases in Japanese river trout and rainbow trout". In these references, it is pointed out that the immune system of fish is quite different from the immune system of other animals. Recent studies have determined that the antibody makeup of fish is quite different to the antibody makeup of other animals and birds. As an example, Teleost fishes possess only one class of antibody, IgM, whereas birds have IgM, IgG(y), IgA and IgD and mammals possess IgM, IgG, IgA, IgD and IgE. Therefore, information regarding other animals such as birds and mammals cannot be readily translated to fish. Thus materials useful in the treatment of conditions in other animals are not necessarily applicable to the treatment of fish.

Therefore, there is nothing in the disclosure of Takahashi et al and Soma et al which would lead the skilled person to arrive at the present invention as a matter of routine. Thus, combining Takahashi et al and Soma et al does not suggest that the use of LMW-LPS in a method of activating immunity, preventing and treating infections in crustaceans or fish is effective. At best, Takahashi et al and Soma et al suggest to try, without a reasonable expectation of success, using LMW-LPS in the method of activating immunity, preventing and treating

infections in crustaceans or fish. It is well established that a mere suggestion to try does not render an invention obvious where there is no reasonable expectation of success.

Also, Takahashi et al discloses a vaccine effective against infectious diseases of crustacea, which contains an effective amount of a glucan and/or mycelium of a glucan producing fungus as an active component. The vaccine contains mycelia of pathogenic bacteria as a base component together with said glucan to demonstrate their synergistic effect depending on the adjuvant activity of the glucan, whereas LPS is an amphiphilic compound comprising both a sugar and a lipid portion. Thus, the LMW-LPS of the present invention is clearly different than glucan. In addition, the HMW-LPS taught in Takahashi et al, although effective in activating immunity, and preventing and treating infections in crustaceans, may be harmful to crustaceans and fish in particular in higher concentrations as disclosed in the present invention. In contrast, the LMW-LPS of the present invention has superior activity in activating immunity, and preventing and treating infections in crustaceans. This allows the amounts of LMW-LPS in the feed or feed additive to be much lower than what would be needed when a similar effect is desired with HMW-LPS. This improvement is not taught or suggested by Takahashi et al or Soma et al either alone or in combination.

Therefore, applicants respectfully submit that the presently claimed invention of claims 18-26, is not obvious over Takahashi et al (US 5,641,761) in view of Soma et al (US 5,494,819). Withdrawal of the rejection is respectfully requested.

Applicants submits that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

RESPECTFULLY SUBMITTED,					
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